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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/521,811 | 04/19/2005 | Immacolata Coraggio | 3687-104 | 3796 |
| 23117 | 7590 | 07/13/2006 | [REDACTED] | EXAMINER |
| NIXON & VANDERHYE, PC | | | | KUMAR, VINOD |
| 901 NORTH GLEBE ROAD, 11TH FLOOR | | | [REDACTED] | ART UNIT |
| ARLINGTON, VA 22203 | | | | PAPER NUMBER |
| | | | | 1638 |

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/521,811 | CORAGGIO ET AL. | |
| | Examiner Vinod Kumar | Art Unit 1638 | |

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 December 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
 - 4a) Of the above claim(s) 5-7 and 9-12 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,8 and 13-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>01/21/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-4, 8 and 13-15 in the paper filed December 30, 2005 is acknowledged. Applicant's arguments filed December 30, 2005 have been fully considered but they are not persuasive. Applicants argue that claims 1-15 are so linked so as to form a single general inventive concept under PCT Rule 13.1, and Y11414 is the special technical feature shared by claims 1-15, and thus claims 1-15 should be examined together (response; page 4, and lines 4-10). Alternatively, Applicants argue that the subject matter of the claims 1-5 and 8-15 is sufficiently interrelated by sharing the same technical feature, and thus should be examined together (response; page 4, lines 17-24). The examiner maintains that restriction requirement is proper because the technical feature linking the inventions of Groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. The examiner further maintains that inventions of Group I-III do not share same special technical feature as communicated in the Office action mailed December 2, 2005. Accordingly, claims 5-7 and 9-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Non-elected subject matter must be removed from the elected claims. This restriction is made FINAL.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449 filed January 21, 2005 is attached to the instant Office action.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Application No. Italy M12002A001624, filed 07/23/2002 has been received.

Claim Objections

4. Claims 8, 14, and 15 are objected to because of the following informalities:
Claims 8, 14, and 15 are objected for depending from non-elected claims.
Appropriate corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4, 8 and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 4, 8, 13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "Y111414 gene", which is confusing, since it is unclear what the recitation "Y111414" means? "Y11414" is a GenBank

accession number. GenBank (NCBI, Sequence database) accession number cannot be used to name a gene. It is unclear what is intended?

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation “the variable region of the Y111414 gene”, which is confusing, since it is unclear what the “variable region of the Y111414 gene” is?

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation “biological vector”, which is confusing, since it is unclear what is intended. A “biological vector” also means a vector that is essential in the life cycle of a pathogenic organism. For example, species of mosquito, serve as vectors for the deadly disease Malaria. It is suggested to replace “biological vector” with --vector--.

Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation “with host cells comprising the Y11414 gene”, which is confusing, since it is unclear what is intended. How plants can be transformed with “host cells comprising the Y11414 gene”? Plants are transformed with a nucleic acid present in *Agrobacterium* cells, not with the cells themselves.

Claims 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being as being incomplete for omitting essential element and/or steps, such omission amounting to a gap between the elements and/or the steps. See MPEP § 2172.01. The preamble is inconsistent with the last recited method step. The preamble recites a method for the treatment and/or prevention of the damages caused by biotic, salt, dehydration, oxidative and osmotic stresses in the plants, whereas last recited method step is introducing the Y11414 gene into said plants. But according to preamble last method step has to be expression of said polynucleotide in the plants.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential element and/or steps, such omission amounting to a gap between the elements and/or the steps. See MPEP § 2172.01. The preamble recites a method for the preparation of stress tolerant transgenic plants, whereas last recited method step is using the Y11414 gene, a functional homologue thereof. But according to preamble last method steps have to be introducing and expression of the Y11414 gene in the plant.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4, 8 and 13-15 are rejected under 35 U.S.C. 112, first paragraph first paragraph, because the specification, while being enabling for a method of producing a stress tolerant transgenic plant comprising transformation of said plant with a Y11414 gene encoding SEQ ID NO: 2, does not reasonably provide enablement for a method to produce a stress tolerant transgenic plant comprising transformation of said plant with a functional homologue, variant of a Y11414 gene or sequences which have less than 100% sequence identity to Y11414 gene sequence. The claims contain subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims are broadly drawn to a method of production of a transgenic plant or a method for the treatment and/or prevention of the damages caused by a biotic or biotic

stresses, comprising transformation of said plant with a Y11414 gene, a functional homologue or variant thereof.

The specification teaches preparation of transgenic plants of *Arabidopsis* transformed with Y11414 gene cDNA operably linked with a CaMV 35S promoter (page 9, lines 18-24). The transgenic plants exhibited high resistance levels to viral (tobacco TNV) and bacterial (*Pseudomonas syringae*) infections (Page 11, lines 1-11). The transgenic plants also exhibited increased tolerance to dehydration, salt and oxidative stresses. See Page 11, lines 14-29 through lines 1-14 of page 12.

Claims 1, 3, 8 and 15 encompass a method of producing a stress tolerant transgenic plant comprising transformation of a plant with a functional homologue or variant of Y11414. Likewise, claim 4 encompasses a method of producing a stress tolerant transgenic plant comprising a polynucleotide sequence that exhibits a sequence homology of at least 70% with the variable region of gene Y11414. The specification provides guidance on using a full-length cDNA sequence of rice Y11414 gene in producing a stress tolerant transgenic plant. The specification does not provide guidance on using homologues, variants or cDNA sequences which have at least 70% sequence identity to rice Y11414 gene to produce a stress tolerant transgenic plant. The homologues, variants or polynucleotide sequences which have less than 100% sequence identity to Y11414 gene would encompass altered version(s) of the Y11414 gene encoding for proteins that are not 100% identical to the protein encoded by the unaltered cDNA of rice Y11414 gene. Furthermore, such alterations in Y11414 gene would encompass more than single amino acid changes in the encoded proteins.

Keskin et al. (Protein Science, 13:1043-1055, 2004) teach that proteins with similar structure may have different functions. Thornton et al. (Nature structural Biology,

structural genomics supplement, November 2000) teach that structural data may carry information about the biochemical function of the protein. Its biological role in the cell or organism is much more complex and actual experimentation is needed to elucidate actual biological function under *in vivo* conditions. Furthermore, Guo et al. (PNAS, 101: 9205-9210, 2004) teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as proteins encoded by a homologue, variant or a polynucleotide sequence having 70% sequence identity to Y11414 gene encompass more than a single amino acid changes in the encoded polypeptide. Thus it would have been highly unpredictable at the time claimed invention was made to make use of variants, homologues or polynucleotide sequences which have 70% sequence identity to Y11414 gene in a method of producing a stress tolerant transgenic plant. Undue experimentation would have been required at the time claimed invention was made to determine how homologues and variants of Y11414 gene or polynucleotide sequences having 70% sequence identity to Y11414 gene can be used to produce a stress tolerant transgenic plant. Neither the state of art nor Applicant provide guidance as to how inoperable embodiments can be readily eliminated other than random trial and error. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would have been required by one skilled in the art to make and use of claimed invention.

Claims 1 and 8 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Element that is critical or essential to the practice of the invention, but not included in the claim is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claims 1 and 8 do not mention expressing any nucleic acid sequence encoding a product that confers increased stress resistance. See MPEP 2164.089(c).

7. Claims 1-4, 8, and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are broadly drawn to a method of production of a transgenic plant or a method for the treatment and/or prevention of the damages caused by a biotic or biotic stresses, comprising transformation of said plant with a Y11414 gene, a functional homologue or variant thereof.

The specification describes preparation of transgenic plants of *Arabidopsis* transformed with Y11414 cDNA encoding SEQ ID NO: 2 operably linked with a CaMV 35S promoter (page 9, lines 18-24). The transgenic plants exhibited high resistance levels to viral (tobacco TNV) and bacterial (*Pseudomonas syringae*) infections (Page 11, lines 1-11). The transgenic plants also exhibited increased tolerance to dehydration, salt and oxidative stresses. See Page 11, lines 14-29 through lines 1-14 of page 12.

Claims 1, 3, 8 and 15 encompass a method of producing a stress tolerant transgenic plant comprising transformation of a plant with a functional homologue or variant of Y11414. Likewise, claim 4 encompasses a method of producing a stress

tolerant transgenic plant comprising a polynucleotide sequence that exhibits a sequence homology of at least 70% with the variable region of gene Y11414. The specification does not have adequate written description for the genus of Y11414 genes, genus of functional homologues of Y11414 gene, genus of variants of Y11414 gene and genus of sequences which have less than 100% sequence identity to Y11414 gene under current written description guidelines. Specification does not describe any of these sequences and one skilled in the art would not have reliably predicted the structure of these sequences based upon the disclosure of Y11414 gene.

Furthermore, said structures of the broadly claimed genus are not correlated to the function of imparting stress tolerance in a transgenic plant. Furthermore, Applicants have failed to describe conserved functional domains that are shared by these undisclosed structures encompassed by the claims. The specification does not reduce to practice any modification of the sequence of Y11414 gene. Accordingly, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus.

Furthermore, claims 1, 3, 4, 8, 13 and 15 and claims dependent therefrom encompass actual genes that encompasses noncoding promoter sequence, coding sequence and 3' region comprising termination and polyadenylation signals. While the specification clearly refers to the coding sequence as a Y11414 gene, the limitation cannot be read into the claim. The specification fails to describe and correlate said structures of a broadly claimed genus to a function. Due to lack of such disclosure, it is evident that Applicants have not established that invention was reduced to practice.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written

Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-4, 8, 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Osnanto et al. (Proceedings of the XLV Italian Society of Agricultural Genetics – SIGA Annual Congress Salsomaggiore Terme Italy – 26/29 September, 2001, Examiner's notice of reference cited in the paper mailed December 2, 2005), taken with the evidence of Pandolfi et al. (Plant Physiol., 114:747, 1997) and Solinas et al. (GenBank, NCBI, Sequence Accession No. Y11414, pages 1-2, Published April 1997).

Osnanto et al. disclose a method of producing a transgenic plant with improved cold tolerance comprising transformation with an expression cassette which comprises an Osmyb4 gene (same as Y11414, as evidenced by Pandolfi et al. and Solinas et al.) into said plant. See the entire article, in particular, last paragraph. The properties of treatment and/or prevention of the damages caused by salt, dehydration, oxidative, osmotic and biotic stresses are inherent to the method disclosed in the reference using said gene.

Accordingly, Osnanto et al. anticipate the claimed invention.

9. Claims 1-4, 8, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexandrov et al. (EP 1033405 A2, Published June 9, 2000).

Alexandrov et al. disclose a method of producing a transgenic plant comprising transformation of said plant with an expression cassette comprising a polynucleotide sequence SEQ ID NO: 69590 which is a functional homolog/variant of instant myb4 (Y11414) gene, wherein said plant is vegetable, such as cucurbita, capsicum etc. See claims 1-34, page 329 and SEQ ID NO: 69590. The properties of treatment and/or prevention of the damages caused by salt, dehydration, oxidative, osmotic and biotic stresses are inherent to the method disclosed in the reference using said gene.

Accordingly, Alexandrov et al. anticipate the claimed invention.

10. Claims 1-4, 8, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Cahoon et al. (US Patent Publication No. 20020066120 A1, Filed November 19, 1999).

Cahoon et al. disclose a method of producing a transgenic plant comprising transformation of said plant with an expression cassette comprising a polynucleotide sequence SEQ ID NO: 37 encoding SEQ ID NO: 38 which is a functional

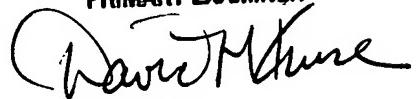
homolog/variant of instant myb4 (Y11414) gene. See claims paragraphs 0003-0005; 0028-0075; claims 61-64. The properties of treatment and/or prevention of the damages caused by salt, dehydration, oxidative, osmotic and biotic stresses are inherent to the method disclosed in the reference using said gene.

Accordingly, Cahoon et al. anticipate the claimed invention

Conclusions

11. No claims are allowed.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).